REMARKS

This application is amended in a manner to place it in condition for allowance at the time of the next Official Action. This amendment is filed with a Request for Continued Examination, as the amendment to the claims is expected to require further consideration and/or search.

Status of the Claims

Claims 1 and 9 are amended. Claim 1 now includes the features of original claim 8. Support may be found, for example in paragraphs [0033]-[0037] and [0043]-{0045].

Claims 13, 14 and 26-34 have been canceled without prejudice as Applicants reserve the right to file one or more divisional applications directed to their subject matter.

Claims 1-5, 7-11, 15, 17-25 remain in this application.

Claims 2-5, 7-11, 15, 19-25 have been withdrawn.

Claim Rejections-35 USC §103

Claims 1 and 17-18 were rejected under 35 U.S.C. § 103(a) as being obvious over MORCOL et al. WO 02/064112 ("MORCOL") in view of KELLER US 6,726,924 ("KELLER") and BAKER et al. US 6,534,018 ("BAKER"). This rejection is respectfully traversed for the reasons below.

The claimed invention is directed to a vector for the oral administration of at least one pharmacologically active substance.

The aim of the invention is to provide such a vector that is able to go through the gastrointestinal tract and to pass across the intestinal wall. The major advantage of the claimed vector is that the vector prevents the active substance from degrading and denaturing during passage across the intestinal wall. Also see, e.g., the present specification at page 6, lines 8-16.

Consequently, it is necessary that the vector is of a size that allows the physical passage of the vector across the intestinal membrane.

This necessary size of the vector is, thus, less than 300 nm, e.g., 200-300 nm as presently recited in claim 1.

It is also essential that the vector remains unchanged before crossing the intestinal membrane. The vector is degraded only after crossing the intestinal membrane, and, thus, allowing the active substance to be released in the blood or in the interstitial fluid, i.e., as recited in claim 1.

These features, however, are neither disclosed nor suggested by the MOROCOL.

For example, MORCOL discloses particles from 300-10µm (claim 3 of MORCOL). Consequently, the larger particles are not of the size be an efficient vector. As a result of the larger

size, the active substance would be partially degraded in the intestine, and, thus, not released into the blood without degradation or denaturation.

MORCOL further differs from the claimed invention by the outer surface of these particles. The particles disclosed by MORCOL are calcium phosphate, which are protected in the acidic environment of the stomach before releasing said agent into the small intestine. MORCOL discloses PEG as surface modifying agent for the surface of the particles, said agent modifying the surface of the calcium phosphate particles (also referred to as core).

These surface modifying agents are used to coat and adhere a therapeutic agent to the formed particle core, but MOROCOL fails to disclose or suggest the modification of the outer surface of said particle core. That is, MORCOL fails to disclose the nature of the bonds between the surface modifying agents (chemical species of claim 1) and the particle core surface (hydrophilic matrix of claim 1).

The presently claimed chemical species modifying the outer surface of the hydrophilic matrix are attached to the matrix by weak bonds, such that the bonds can be detached from the matrix by contact with the microvilli present in the intestine and during the passage through the intestinal barrier. The detachment of the chemical species from the matrix thus

allows the latter to return to its essentially hydrophilic nature.

Thus, MORCOL does not disclose the attachment of chemical species to the matrix via weak bonds that give the vector an essentially lipophilic nature as required in claim 1.

MORCOL does not teach the particles as being contained in an additional lipophilic compound. Thus, MORCOL does not disclose the use of a lipophilic medium as being an additional protection from the external aqueous medium.

Such additional protections (lipophilic compound for gastric protection and chemical species for modifying the surface of the matrix) are essential to allow the pharmacologically active substance to pass through the intestinal barrier and then to be available in the blood. This function that results from the matrix and chemical species is recited in claim 1.

Thus, the present invention is based on a system for the administration of a pharmacologically active substance to pass from the intestinal lumen to the blood.

However, as discussed above, MORCOL is provides delivery of the small intestine but not in the blood.

For these reasons, MORCOL fails to disclose or even suggest the claimed invention.

KELLER and BAKER fail to remedy the deficiencies of MORCOL for reference purposes.

KELLER discloses the encapsulation of an active substance in a liposome, said liposome being in particular protected with a gelatin shell, which may also be coated with a cellulosic polymer.

BAKER discloses lipidic vesicles comprising an active substance encapsulated in either the aqueous core or within the lipidic bilayer of said vesicles.

Neither discloses or suggests the claimed size of particles or the claimed bonds between the matrix containing the active substance and a chemical species modifying the outer surface of said matrix.

Thus, at best, the combination teaches administration of an active substance in the small intestine, and not administration that allows the active substance to pass through the intestine into the blood as required in claim 1. Indeed, there is no suggestion to modify of a matrix as claimed to enable such a function.

Therefore, withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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